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Actavis Elizabeth LLC, Mylan Inc.,  
Mylan Pharmaceuticals, Inc.,  
Mylan Bertek Pharmaceuticals, Inc.  
and UDL Laboratories, Inc..*

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY  
Newark Vicinage

GEORGE PALLADINO,

Plaintiff,

v.

ACTAVIS TOTOWA LLC, ACTAVIS  
INC., ACTAVIS ELIZABETH LLC,  
ACTAVIS US, MYLAN, INC., MYLAN  
PHARMACEUTICALS, INC., MYLAN  
LABORATORIES, INC., MYLAN  
BERTEK PHARMACEUTICALS, INC.,  
and JOHN DOE DEFENDANTS 1-20,

Defendants.

Civil Action

Case No.:

**NOTICE OF REMOVAL**

Defendants Actavis Totowa LLC, Actavis Inc., Actavis Elizabeth LLC, Mylan Inc. (formerly known and incorrectly sued as Mylan Laboratories, Inc.), Mylan Pharmaceuticals, Inc., Mylan Bertek Pharmaceuticals, Inc. and UDL Laboratories, Inc. (“Defendants”) respectfully submit this Notice of Removal pursuant to 28 U.S.C. §§ 1332, 1441, 1446 and 1453. In support of removal, Defendants state as follows:

**I. PROCEDURAL REQUIREMENTS FOR REMOVAL ARE MET**

1. On or about June 11, 2008, the Class Action Complaint naming Defendants was filed in the Superior Court of New Jersey, Atlantic County captioned *Palladino v. Actavis Totowa LLC, et al.*, Docket No. L-1881-08 (the “State Court Action” or “Complaint”). A copy of the Complaint is attached as Exhibit A. No other pleadings are known to have been filed in the State Court Action.

2. On or about July 24, 2008, several of the Defendants received copies of a Summons and Complaint in this matter. Upon information and belief, however, not all appearing Defendants have been served with the Summons and Complaint.

3. This is one of several individual actions and putative class actions filed involving allegations regarding the prescription drug Digitek®. Presently before the Judicial Panel for Multidistrict Litigation (“JPML”) are several motions seeking the transfer of these cases to a centralized MDL court. Defendants did not oppose the transfer of these actions to a centralized MDL court for coordinated pretrial proceedings. A decision from the JPML is expected shortly and Defendants will thereafter provide the JPML with notice of this action pursuant to the “tag-along” procedure provided for in the JPML Rules.

4. As is more fully set forth below, this case is properly removed to this Court pursuant to 28 U.S.C. § 1441 because Defendants have satisfied the procedural requirements for removal and this Court has subject jurisdiction over this action pursuant to 28 U.S.C. § 1332.

5. Defendants have satisfied the procedural requirements to removal. Removal is timely. This Notice of Removal is filed within thirty (30) days of the date the first Defendants

were purportedly served with a copy of the Complaint, and it is therefore timely pursuant to 28 U.S.C. § 1446(b).

6. Upon information and belief, no further proceedings have occurred in the State Court Action.

7. Defendants Actavis Totowa LLC and Actavis Elizabeth LLC have made no previous application for this or similar relief.

8. Although the pseudonymously named “Doe” defendants have not been identified and thus their consent to remove could not be obtained, under 28 U.S.C. § 1453, a class action “may be removed by any defendant without the consent of all defendants.” In any event, a removing party is not required to obtain the consent of fraudulently joined, fictitious, or unserved parties. *Balazik v. County of Dauphin*, 44 F.3d 209, 213 & n. 4 (3d Cir. 1995); *Gilberg v. Stepan Co.*, 24 F. Supp. 2d 325, 329 & n. 2 (D.N.J. 1998).

9. Venue is proper.

10. The written notice required by 28 U.S.C. 1440(d) will be promptly filed in the Superior Court of New Jersey, Atlantic County, Law Division and served on Plaintiff’s counsel.

## **II. REMOVAL IS PROPER IN THIS CASE**

### **A. This Action is Removable Under CAFA**

11. This civil action is subject to removal under the provisions of the Class Action Fairness Act of 2005 (“CAFA”), 28 U.S.C. § 1453.

12. CAFA adds §1453 to Title 28 of the U.S. Code, which provides in relevant part:

A class action may be removed to a district court in the United States in accordance with section 1446...without regard to whether any defendant is a citizen of the State in which the action is being brought, except that such action may be removed by any defendant without consent of all defendants.

13. Section 1453 applies to “any civil action commenced on or after the date of enactment of [CAFA]” February 18, 2005. Federal courts define “commenced” to refer to the date the action was commenced in federal court by the filing of a notice of removal. *Adamar of New Jersey, Inc. v. Karabell*, 719 F. Supp. 1251, 1253 (D.N.J. 1989); *Sayers v. Sears, Roebuck and Co.*, 732 F. Supp. 654, 655-56 (W.D. Va. 1990).

14. Plaintiff filed his Complaint on or about June 11, 2008, after the enactment of CAFA.

15. CAFA amends the federal diversity jurisdiction statute, 28 U.S.C. § 1332, to give federal district courts original jurisdiction over any class action in which: a) “Any member of a class of plaintiffs is a citizen of a State different from any defendant”; b) the number of class members is at least 100; and c) the aggregate in controversy is more than \$5 million, exclusive of interest and costs.

16. Plaintiff is allegedly a New Jersey resident. (Compl. at ¶ 4.) In contrast, defendant Mylan Inc. is a Pennsylvania corporation with a principal place of business in Pennsylvania; defendant Mylan Pharmaceuticals, Inc. is a West Virginia corporation with a principal place of business in West Virginia; and defendant Mylan Bertek Pharmaceuticals, Inc. is a Texas corporation with no principal place of business since it closed its facilities in North

Carolina in 2005. Thus, Plaintiff is a citizen of a state that is different from more than one defendant.

17. Plaintiff defines the putative class as “himself and all other similarly situated persons residing in the State of New Jersey, who were prescribed and ingested the recalled Digitek®, who claim no personal injuries and who claim the likelihood of undetected or latent personal injuries and who seek medical monitoring as a result of the ingestion of the recalled Digitek®.” (Compl. at 12, ¶ 5; see also ¶ 69.)

18. In paragraph 58 of the Complaint, Plaintiff alleges that Defendants placed “many thousands of patients, including Plaintiff and the class unnecessarily at significantly increased risk of serious injury and/or death.” In support of these class allegations, Plaintiff claims that the members of the class are “so numerous that joinder is impracticable and would involve a large number of individual actions.” (Compl. at 15-16 ¶ 70.)

19. Plaintiff defines the applicable class time period as that time “when the recalled Digitek® was marketed, designed, manufactured, produced, distributed, released, sold, or otherwise supplied.” (Compl. at 15, ¶ 69.) Because Plaintiff’s definition of the class is “[a]ll persons residing in the State of New Jersey who,” during this time period “have not suffered personal injuries arising from the ingestion of the recalled Digitek®,” the class includes all recent Digitek® users residing in New Jersey. (*Id.*) Based on these and other allegations alone, the number of class members is clearly intended to be very numerous and exceed 100.

20. The jurisdictional threshold is reached from the face of the Complaint as well and it cannot be reasonably disputed that the jurisdictional amount \$5 million cannot be awarded as pleaded. Plaintiff seeks numerous types of equitable relief and monetary damages including: A

preliminary injunction or other order providing for equitable notice to all members of the class; an order compelling Defendants to pay for past medical evaluation already obtained by the members of the class; an order compelling Defendants to pay for the cost of recalled Digitek®; an order compelling Defendants to pay ascertainable losses, treble damages, attorneys' fees and costs under the New Jersey Consumer Fraud Act; an order compelling a follow-up Epidemiology Study to be funded by Defendants; an award of pre- and post-judgment interest; any and all damages available by statute or common law; an award to Plaintiff and the putative class members of punitive damages; and attorneys' fees, costs and expert fees. (Compl. at 32, ¶¶ 3-13.)

21. The equitable relief and monetary damages requested by Plaintiff and the putative class exceed, in the aggregate, the statutory jurisdictional amount of \$5 million. In the absence of precise damages calculations, the following variables may be assessed to compute the amount in dispute: the cost of past medical evaluation; the cost of recalled Digitek®; the number of class members; ascertainable losses and treble damages; the amount of allowable punitive damages; attorneys' fees; the cost of a follow-up epidemiology study; and pre- and post-judgment interest, costs and expert fees. *See, e.g., Faltaous v. Johnson and Johnson*, No. 07-1572, 2007 WL 3256833, at \*7 (D.N.J. Nov. 5, 2007), attached as Exhibit B.

22. For the purposes of determining whether the jurisdictional threshold is exceeded, and without admitting the amount of damages that may be recovered by any individual plaintiff or putative class member, the costs of the equitable and monetary relief sought may be estimated. *Id.* The costs of the recalled Digitek® and past medical evaluations alone could reach \$5,000,000 without the need calculating any other possible relief. For one plaintiff, medical

evaluation would involve at least one doctor's office visit, at approximately \$150, and might also entail laboratory and other tests, which could reasonably cost up to \$500. A one-month supply of Digitek® would cost a typical consumer approximately fifty dollars, although some Digitek® consumers who buy their prescriptions in bulk may have had more than a one-month supply on hand. Even assuming that, at the very least, most consumers purchase a one-month supply at a time, the cost of recalled Digitek® and past medical evaluation could be estimated at between \$200 and \$700 per class member. Plaintiff asserts that defendants placed at risk "many thousands of patients." (Compl. at 13, ¶ 58.) At a conservatively estimated recovery of \$700 per class member, the class would only have to include approximately 7,150 members to reach the jurisdictional minimum.

23. Plaintiff further seeks treble damages under the New Jersey Consumer Fraud Act. If awarded, and assuming ascertainable losses of \$700 per class member, each class member could recover up to \$2,800. The class would only have to include approximately 1,800 plaintiffs to reach the jurisdictional minimum.

24. New Jersey statutory authority allows punitive damages up to five times the amount of compensatory damages. N.J. Stat. §2:A:15-5.14(b). If the maximum were awarded, and assuming compensatory damages of \$700 per class member as calculated above, each plaintiff could recover \$4,200, thus only requiring approximately 1,200 members to reach the jurisdictional minimum. Assuming more conservatively that punitive damages could increase each class member's total recovery to a more modest \$1,200, the class would only have to include approximately 4,200 plaintiffs to reach the jurisdictional minimum.

25. Attorneys' fees may also be calculated to be as much as thirty percent of a presumptive judgment. *Frederico*, 507 F.3d at 199; see also *In re Rite Aid Corp. Securities Litigation*, 396 F.3d 294, 303 (3rd Cir. 2005) (noting Federal Judicial Center study finding a median percentage recovery range of 27-30% for all class actions resolved or settled over a four-year period). Thirty percent of a per class member judgment of \$4,200 is \$1,260, totaling up to \$5,460. If this amount were awarded, the class would only have to include less than one thousand plaintiffs to reach the jurisdictional minimum.

26. Plaintiff also seeks a follow-up epidemiology study to be funded by defendants. To be adequately powered, such a study would have to include hundreds, possibly thousands, of subjects over a period of many months or years. A follow-up epidemiology study has the reasonable potential to cost one or two million dollars or more. The costs of litigation, exclusive of attorneys' fees, and pre- and post-judgment interest on the total potential recovery could also total hundreds of thousands of dollars or more. For jurisdictional purposes, this presumptively awarded relief would further increase to potential recovery amounts for individual class members.

27. For these reasons, there is no legal certainty and plaintiff cannot show that the jurisdictional amount \$5 million cannot be awarded.

28. Because all three CAFA jurisdictional requirements are met, this action is removable under 28 U.S.C. § 1453.



**B. None of the Statutory CAFA Exceptions Apply**

29. CAFA provides exceptions to its expansion of federal jurisdiction for homestate and local controversies. Neither exception applies to preclude federal jurisdiction in this action. 28 U.S.C. §§ 1332(d)(3), (4).

30. Under the homestate controversy exception, federal courts may at their discretion decline to exercise jurisdiction when the primary defendants are citizens of the state in which the action was originally filed, despite satisfaction of the three primary jurisdictional criteria set forth in Paragraph 11 of this Notice. 28 U.S.C. §§ 1332(d)(3).

31. Although the Actavis Defendants have principal places of business in New Jersey, the other primary Defendants, Mylan Inc., Mylan Pharmaceuticals, Inc. and Mylan Bertek Pharmaceuticals, Inc. do not. Plaintiff asserts that the Mylan defendants were in the business of, and did profit from, marketing, design, development, manufacture, production, processing, compounding, formulating, testing, sale, labeling, packaging, dosing advertisement, promotion, supply and/or distribution of Digitek®. (Compl. at 5, ¶ 18.) Plaintiff's assertions against the Mylan defendants are substantially similar to the assertions against the Actavis defendants. For the purposes of jurisdiction under CAFA, therefore, the Mylan defendants' status as primary defendants is indistinguishable from that of the Actavis defendants. Because the Mylan defendants are primary defendants and are not citizens of New Jersey, the state in which this action was brought, the homestate controversy exception may not be applied.

32. The local controversy exception precludes federal subject matter jurisdiction when only one defendant is a citizen of the State in which the action was originally filed, but only if no other class action has been filed asserting similar factual allegations against any of the

defendants on behalf of the same or other persons during the preceding the three-year period. 28 U.S.C. §§ 1332(d)(4).

33. The local controversy exception does not apply to this action, despite the fact that some of the defendants in this action are New Jersey citizens, because at least eight other class actions have been filed stating similar allegations against the same defendants and on behalf of the same or other persons. 28 U.S.C. §§ 1332(d)(4). *See White v. Actavis Totowa, LLC, et al.*, Civil Action No.: 4:08-cv-00320-DW, U.S. District Court, Western District of Missouri (May 2, 2008); *Thrasher v. Actavis Group, et al.*, Civil Action No.: 08-3167, U.S. District Court, Eastern District of Louisiana (May 5, 2008); *Clark v. Actavis Group, et al.*, Civil Action No.: 2:08-cv-2293, U.S. District Court of New Jersey (May 9, 2008); *Bull v. Actavis Group, et al.*, Civil Action No.: 2:08-cv-396-FtM-29DNF, U.S. District Court, Middle District of Florida (May 14, 2008); *Becnel v. Actavis Group, et al.*, Civil Action No.: 08-3431, U.S. District Court, Eastern District of Louisiana (May 15, 2008); *Heinzman v. Actavis Group, et al.*, Civil Action No.: 2:08-cv-00480, U.S. District Court, Southern District of Ohio (May 19, 2008); *Konek v. Actavis, Inc., et al.*, Civil Action No.: 6:08-cv-1145-MLB-KMH, U.S. District Court of Kansas (May 19, 2008); *Stanley v. Actavis Group, et al.*, Civil Action No.: 3:08-cv-01321-JZ, U.S. District Court, Northern District of Ohio (May 30, 2008).

### III. SUBSTANTIAL FEDERAL QUESTION JURISDICTION

34. Federal courts have original jurisdiction in any civil action founded on a claim or right arising under the federal law, and these actions are removable without regard to diversity of the parties. 28 U.S.C. §1441(b). A case arises under the federal law if the complaint establishes that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law. *Grable & Sons Metal Products, Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005) (“[t]he doctrine captures the common sense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.”); *Northeast Dept. ILGWU Health and Welfare Fund v. Teamsters Local Union No. 229 Welfare*, 764 F.2d 147, 157 (3rd Cir. 1985) (An action arises under federal law “if the complaint seeks a remedy [that] requires the construction of a federal statute or a distinctive policy of a federal statute requires the application of federal legal principles for its disposition.”).

35. Plaintiff's request for equitable relief – in the form of an order and a preliminary injunction compelling Defendants to violate the mandatory FDA-approved recall process – necessarily “raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” *Grable*, 545 U.S. at 314 (framing the issue for federal question jurisdiction inquiry).

36. Specifically, Plaintiff requests an order and a preliminary injunction “to provide the plaintiff and class members with sufficient information and Notice appropriate for them to

make informed decisions related to their physical well-being and to maintain possession of the Digitek® and related paperwork,” (Compl., ¶¶ 66, 78), in violation of the mandatory FDA-approved recall process under 21 C.F.R. §§ 7.40-.59. See also Compl. at 31-32, ¶¶ 1-3, outlining equitable relief demanded.

37. This request for equitable relief triggers the outcome determinative interpretation of federal regulations in this action. That is, the meaning and effect of 21 C.F.R. §§ 7.40-.59 and 21 C.F.R. § 10.30 (governing citizens’ petitions to request the Commissioner to issue, amend, or revoke an order and providing vehicle for citizens to provide exact wording requested for purposed orders) is directly in issue, and presents a substantial question of federal law. Plaintiff’s right to equitable relief depends on resolution of these federal questions. *See, e.g., In re Human Tissue Prods. Liab. Litig.*, 488 F. Supp. 2d 430 (D.N.J. 2007) (deferring to the exclusive jurisdiction and competence of the FDA on the issue of providing notice to unnamed class members):

As these regulations show 21 C.F.R. [§§ 7.40-.59] Congress clearly vested the FDA with the regulatory authority to assess and manage the communications regarding product recalls. Implicit in this authority is the understanding that the FDA possesses the necessary expertise to determine when notice is required, what the notice should contain, and who the notice should be sent to. By requesting the court to issue a similar notice here, plaintiffs are essentially asking the court to perform the tasks traditionally relegated to the FDA.

448 F. Supp. 2d at 433.

38. Because Plaintiff’s claim for equitable relief necessarily turns on resolution of substantial questions of federal law, this Court has original jurisdiction over this action under 28 U.S.C. § 1441(b).

39. Accordingly, Defendants respectfully remove this action to this Court from the Law Division of the Superior Court of New Jersey in and for Atlantic County. Defendants pray for such other and further relief to which they may be entitled, both at law and in equity, both general and special.

Dated: August 11, 2008

Respectfully submitted,

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